November 22, 2021

Mary Ann Fiechtner
Staff Regulatory Affairs Specialist – Point of Care
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

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| Device: | BD Veritor At-Home COVID-19 Test |
| EUA Number: | EUA210417 |
| Company: | Becton, Dickinson and Company (BD) |
| Indication: | Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with:<br>Self-collected anterior nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.<br>Adult collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.<br>Self-collected anterior nasal swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.<br>The test results are interpreted by the Scanwell Health App and displayed on a compatible smartphone. |

Dear Ms. Fiechtner:

On August 24, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the BD Veritor At-Home COVID-19 Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.[2]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Becton, Dickinson and Company

[2] The August 24, 2021, letter authorized the BD Veritor At-Home COVID-19 Test for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other

On October 29, 2021, you requested to amend this EUA. Based on that request, and having concluded that revising the August 24, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the August 24, 2021, letter in its entirety with the revisions incorporated.[3] Accordingly, your product[4] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[5]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "BD Veritor At-Home COVID-19 Test Healthcare Provider Instructions for Use" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

**I. Criteria for Issuance of Authorization**

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epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours but not more than 48 hours between tests. The test results are interpreted by the Scanwell Health App and displayed on a compatible smartphone. This test is authorized for non-prescription home use with self-collected (unobserved) direct anterior nasal swab specimens from individuals aged 14 years or older, or with adult collected anterior nasal swab specimens from individuals aged 2 years or older.

[3] The revisions to the August 24, 2021, letter and authorized labeling include: (1) updates to the intended use to include use of your product with "*self-collected anterior nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset*," "*adult collected anterior nasal swab samples from individuals aged 2 years or older, with symptoms of COVID-19 within the first 7 days of symptom onset,*" and "*self-collected anterior nasal swab samples from individuals aged 14 years or older, or with adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests,*" (2) update the outer box labels and Instructions for Use (IFU) limitations section to reflect the updates to the intended use, and (3) updates consistent with language used in more recent authorizations.

[4] For ease of reference, this letter will use the term "your product" to refer to the BD Veritor At-Home COVID-19 Test used for the indication identified above.

[5] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[6]

**II. Scope of Authorization**

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

**Authorized Product Details**

Your product is a chromatographic, digital immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. The test results are interpreted by the Scanwell Health App and displayed on a compatible smartphone.[7]

This test is authorized for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult collected anterior nasal swab samples from individuals aged 2 years or older, with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older, or with adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. Your product does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results

[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[7] Compatible smart phone includes the following minimum requirements: Apple iPhone 7 and newer models, running Operation System (iOS) 10 or later versions of the iOS and a camera resolution of at least 1000 pixels in both dimensions, Android phones with Android 9 or higher and a camera with a resolution of at least 1000 pixels in both dimensions that supports RAW image capture, manual exposure and sensitivity settings, and additional smart phone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition L. below.

indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Test results are reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC). Test result reporting from the BD Veritor At-Home COVID-19 Test occurs via the Scanwell Health App software application. Individuals should also report their test result to their healthcare provider to receive appropriate medical care.

Your product is performed using anterior nasal swab specimens from individuals aged 14 years or older or adult collected anterior nasal swab specimens from individuals age 2 years or older. First, the individual is instructed to read the Quick Start Guide (QSG), download and open the Scanwell Health App on a compatible smartphone, and create or login to their Scanwell Account. The Scanwell Health App then guides the user through the entire test procedure, from test preparation through nasal swab sample collection, sample extraction/processing, sample application to the Test Stick and finally Test Stick scanning and results interpretation, using audio as well as written and video step-by-step instructions. Once collected the anterior nasal swab specimen is added to the Tube containing extraction fluid and the extracted specimen is then added to the Test Stick, SARS-CoV-2 nucleocapsid antigens present in the specimen bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the test reaction area and are captured by a line of antibodies

bound to the membrane. The Test Sticks are designed with spatially distinct reaction zones which include distinct positive and negative control line positions, a sample adequacy line position and the test line position for SARS-CoV-2. Interpretation and report of the correct test result, from the multiple lines deposited in the reaction zone, requires the use of the Scanwell Health App to process a scanned image of the Test Stick and provide the results to the individual running the test. Upon completion of the test and result interpretation the user should share their results with their healthcare provider.

The BD Veritor At-Home COVID-19 Test kit includes the following materials or other authorized materials: Tube(s) containing extraction fluid, Box with Tube Holder, Nasal Swab(s), Test Stick(s), Scan Card(s), Quick Start Guide, Product Information Leaflet, and Fact Sheet for Individuals.

Your product includes spatially distinct reaction zones which include distinct positive and negative internal control line positions along with a sample adequacy line position that must generate the expected result for a test to be considered valid, as outlined in the "BD Veritor At-Home COVID-19 Test Healthcare Provider Instructions for Use."

The labeling entitled "BD Veritor At-Home COVID-19 Test Healthcare Provider Instructions for Use," the "BD Veritor At-Home COVID-19 Test Product Information Leaflet," the "BD Veritor At-Home COVID-19 Test Quick Start Guide," and the "BD Veritor At-Home COVID-19 Test" box label (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "Scanwell Health App" software application, and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Professionals: BD - BD Veritor At-Home COVID-19 Test
- Fact Sheet for Individuals: BD - BD Veritor At-Home COVID-19 Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in

Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

## III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

## IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

### Becton, Dickinson and Company (You) and Authorized Distributor(s)[8]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "BD Veritor At-Home COVID-19 Test Product Information Leaflet," the "BD Veritor At-Home COVID-19 Test Quick Start Guide," and the "Fact Sheet for Individuals" for your product in the shipped kit using the "BD Veritor At-Home COVID-19 Test" box label and also make these three documents in the shipped kit electronically available on your website.

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

[8] "Authorized Distributor(s)" are identified by you, Becton, Dickinson and Company, in your EUA submission as an entity allowed to distribute your product.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

**Becton, Dickinson and Company (You)**

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "BD Veritor At-Home COVID-19 Test Healthcare Provider Instructions for Use" and the "Fact Sheet for Healthcare Professionals" electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "BD Veritor At-Home COVID-19 Test Healthcare Provider Instructions for Use" and "Fact Sheet for Healthcare Professionals" in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such

additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[9] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You must submit a final agreed upon real-time stability study design within 30 days of the date of this letter and then complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. You must submit a final agreed upon shipping stability study design within 30 days of the date of this letter and then complete the agreed upon shipping stability study for your product within 3 months of the date of this letter (unless otherwise agreed to with

[9] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

DMD/OHT7-OIR/OPEQ/CDRH). After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

T. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately.

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

**Conditions Related to Printed Materials, Advertising and Promotion**

V. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

W. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

X. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure